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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/522,401	01/19/2005	Taishi Yoshida	04818CIP/HG	6305

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FRISHAUF, HOLTZ, GOODMAN & CHICK, PC
220 Fifth Avenue
16TH Floor
NEW YORK, NY 10001-7708

EXAMINER	
FINN, MEGHAN R	

ART UNIT	PAPER NUMBER
1609	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/522,401	YOSHIDA ET AL.	
	Examiner	Art Unit	
	Meghan Finn	1609	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 June 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6 and 8-29* is/are pending in the application.

4a) Of the above claim(s) *6,8-12 and 24* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,13-23 and 25-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *19 January 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/19/05, 5/03/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's election without traverse of claims 1-5, 13-23, and 25 in the reply filed on June 14, 2007 is acknowledged. Claims 6, 8-12, and 24 are withdrawn from consideration. Applicant canceled claim 7 and added new claims 26-29 in amendment filed on June 26, 2007. Claims 1-5, 13-24, 25-29 are examined and rejected.

Specification

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

Claim Objections

Claim 10 objected to because of the following informalities: Claim 10 is not part of the elected group I, and thus should be withdrawn as being part of the non-elected invention. Appropriate correction is required.

Double Patenting

Claims 1-2 of this application conflict with claim 7 of application No. 11/792879. Claims 4-5, and 26 of this application conflict with claim 31 of application No. 11/792879. Claims 18-20 of this application conflict with claim 29 of application No. 11/792879. 37 CFR 1.78(b) provides that when two or more applications filed by the

same applicant contain conflicting claims, elimination of such claims from all but one application may be required in the absence of good and sufficient reason for their retention during pendency in more than one application. Applicant is required to either cancel the conflicting claims from all but one application or maintain a clear line of demarcation between the applications. See MPEP § 822.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to

be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-2 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 7 of copending Application No. 11/792879. Although the conflicting claims are not identical, they are not patentably distinct from each other because they both describe treating diabetes mellitus with a treatment comprising a FBPase Inhibitor.

Claims 4-5 and 26 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 31 of copending Application No. 11/792879. Although the conflicting claims are not identical, they are not patentably distinct from each other because they both teach using the same FBPase inhibitor to treat diabetes mellitus. In application number 11/792879 the specific compound 2-amino-5-isobutyl-4-{2-[5-(N,N'-bis((S) –1-ethoxycarbonyl)ethyl)phosphonamido]furanyl}thaizole which is included in the generic structures of formula (I) in claim 4 and formula (Ia) in claim 5. It is also the same compound named in claim 26 and thus claims 4-5, and 26 are unpatentable over claim 31 of application 11/792879.

Claims 18-20 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 29 of copending Application No. 11/792879. Although the conflicting claims are not identical, they are not patentably distinct from each other because they both describe a method of treating diabetes with an FBPase inhibitor with dosages in the range of 10mg to 200mg. Applicant's invention describes a larger range, but claims 18-20 are encompassed by the range described in claim 29 of application number 11/792879 and thus are unpatentable over each other.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-5, 13-23, 25-29 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Prevention of diabetes is a goal, but is not known to be possible by those skilled in the art at the time of applicant's invention. Gillespie et al. (Type 1 diabetes: pathogenesis and prevention) teaches that not only is the cause of type 1 diabetes still undefined but no known prevention of type I diabetes exists even as late as July 2006 (page 165, abstract). They also cite several large scale prevention studies that yielded negative results, indicating that while a method of prevention may be soon in the future as of 2006 is was not a reality yet (page 168, paragraphs 1-4). Applicant has shown treatment, but not prevention of diabetes.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-2, 4-5, 14, 18-23, and 25-29 are rejected under 35 U.S.C. 102(b) as being anticipated by Van Poelje et al. (WO 02/03978 A2).

Claims 1-2, 4-5, and 14 describe a method of treating diabetes with an FBPase inhibitor, and in claims 4-5 that inhibitor is narrowed to the general formulas of (I) in

claim 4 and (Ia) in claim 5. Van Poelje et al. teaches a general formula for an FBPase inhibitor that reads on both formulas (I) and (Ia) (formula IA, page 26, line 26) and teaches the use of their invention to treat diabetes and other diseases related to glycemic control (page 5, line 1).

In claims 18-20, the applicant describes a dosage of 0.001 to 2000mg/day in claim 18, narrows it to 0.01-200mg/day in claim 19, and further narrows it to 0.1 to 20mg/day in claim 20. Van Poelje et al. teaches a range of 5-2500mg of their FBPase inhibitor, which would read on claims 18-20. It is also worth noting that both applications have such large dosage ranges that the two ranges would have been considered obvious variants of each other to those skilled in the art at the time of the invention.

Claims 21-23, and 25 are composition claims for a general FBPase inhibitor and to those products of formulas (I) and (Ia). Since Van Poelje et al. not only teaches a method of treatment with the compounds that encompass those of formulas (I) and (Ia) (page 354, line 6) but also the synthesis (page 234) and pharmaceutical compositions (page 334, line 19) for those compounds as well. Thus Van Poelje et al. anticipated claims 23-23, and 25 of applicant's invention.

Claims 26-29 of applicant's invention are directed to specific embodiments of the general structure described in formula (I) of claim 4. As discussed supra, Van Poelje et al anticipates the method of treatment described in claim 1, and all 4 specific structures are covered by the invention described in Van Poelje et al (page 116, line 9). The

general structure on page 116 is specified on the following pages, to include the compounds described in claims 26-29:

R12 can be H, methyl, or ethyl (page 121, table C)

R13 can be H, methyl, or ethyl (page 122, table D)

X4 can be 2,5-furanyl (page 125, table G),

R14 can be OR17 (page 139, table Q)

R17 can be lower alky, methyl, or ethyl (page 139, table Q)

R18 can be H (page 139, table Q)

R55 can be a substituted thaizolyl (page 138, table Q)

The R55 group is further specified (page 161, line 13), where the thaizolyl is R5, group 1, option 1 and A is NH2 (option 1) and B is either –iBu (option 2) or –S-nPr (option 4).

The specific groups described above encompass those structures named in claims 26-29, specifically the amino group as R1a, the isobutyl and the propylthio for R5a, the ethyl and methyl for R2a and R3a and the ethyl for R4a of applicant's formula (I). Thus claims 26-29 are anticipated by Van Poelje et al.

Claims 1, 3 and 17 are rejected under 35 U.S.C. 102(e) as being anticipated by Jiang et al. (US 6,965,033).

Claims 1, 3 and 17 describe a method of using an FBPase inhibitor to treat diseases macroangiopathy or arteriosclerosis. Jiang et al. teaches that a FBPase inhibitor of formula (IA) (page 2, column 2, line 61) which the same as formula I

described in applicant's claim 4. Jiang et al also teaches that their invention can be used to treat diabetes (abstract, page 1) and other cardiovascular diseases such as atherosclerosis which is a type of arteriosclerosis (page 2, column 2, line 52). Thus Jiang et al. anticipates the treatment of cardiovascular diseases such as arteriosclerosis as described in claims 3 and 17.

Conclusion

No claims are allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Dang et al. and Erion et al. are relevant to applicant's invention and as such are cited to show the state of the art at the time of the invention.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.\

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Meghan Finn whose telephone number is (571) 270-3281. The examiner can normally be reached on 7:30am-5pm Mon-Thu, 7:30am-4pm Friday (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker can be reached on 571-272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Meghan Finn

MICHAEL MELLER
PRIMARY EXAMINER